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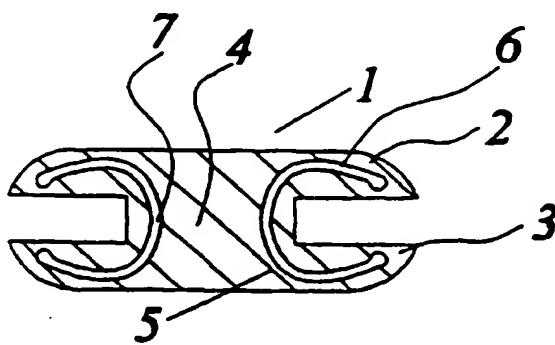
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(54) Title: AN OCCLUDER WITH ANCHOR



(57) Abstract: A transcatheter occluder device (1) for closing an opening in a tissue wall for the repair of cardiac defect has a body member formed of an open cell polymer foam which can be held in a desired occluder shape but is resiliently compressed for transcatheter deployment. The defect occluder (1) comprises a pair of spaced-apart discs (2, 3) joined by a narrow plug (4). Encapsulated within the body member are three spaced-apart reinforcing and anchoring clips (5) of substantially C-shape each having a pair of retaining arms (6) projecting from a central support stock (7). Because the anchoring clips (5) are separate, there is no kinetic loading on one anchorage clip (5) due to the movement of another anchorage clip (5). The anchorage clips (5) will therefore move with the issue wall.

WO 01/10306 A1

- 1 -

AN OCCLUDER WITH ANCHOR

Introduction

- 5 The present invention relates to a defect occluder for the repair of cardiac defects and the like in humans or animals. In particular the defect occluder is for closing an opening in a tissue or vessel wall. The opening may be a through-hole or a cavity.
- 10 More particularly the invention relates to a transcatheter occluder device for closing an opening in a tissue wall or a vessel wall, the device comprising: -
- 15 a body member formed from a material which is substantially self-supporting to hold a desired occluder shape, but is resiliently compressible for transcatheter deployment;
- the material being a biologically compatible material or coated with a biologically compatible material;
- 20 the body member including a plug for closing the opening; and
- the body member having retaining means for retaining the plug in the opening.
- 25 This particular form of defect occluder was first described and claimed in PCT Application No. PCT/IE97/00037 (WO-A-97/41778). This occluder device overcame many of the problems of previously used occluder devices which generally comprised some form of frame incorporating stainless steel or Nitinol, one of the problems of which was that such frames are subjected to metal fatigue

- 2 -

under the normal kinetic loading, or cyclical fatigue loading that occurs for example in cardiac applications. In previous teachings it was acknowledged that the anchoring and retention of the device in defect openings may not in all instances rely solely on the properties of the structural foam. Depending on the
5 specific application, the implant design might be too bulky if reliant on foam properties to secure it in position. It was appreciated that the addition of metallic elements in appropriate configurations would allow device reinforcement and thus assist in anchoring in smaller sized configurations of a device, which is beneficial.

10

The above referred to patent application showed a version of the occluder with metallic elements acting as reinforcement, however, the occluder described is not suitable for dynamic load conditions. The fact that the support arms are connected to a central core means that in a septal application, the heartbeat
15 would apply a cyclical load to the support structure.

Ideally the occluder devices to which the present invention relates should preferably include some additional reinforcing, or metal or the like fixing means, while at the same time obviating the same problems of metal fatigue.

20

The present invention is directed towards providing such a defect occluder.

Statements of Invention

25 According to the invention there is provided a defect occluder for closing an opening in a tissue or a vessel wall, the device comprising:-

30 a body member formed from a material which is substantially self-supporting to hold desired occluder shape, but is resiliently compressible for transcatheter deployment;

- 3 -

the body member being formed of or at least coated with a biologically compatible material;

5 the body member including a plug for closing the opening; and

the body member having retaining means for anchoring the plug in the opening generally provided by the shape and resilience of the material;

10 characterised in that a separate anchorage clip is incorporated in the body member.

The retaining means incorporated in the plug is generally provided by the shape and resilience of the material of the body member.

15 Preferably there are at least two separate anchorage clips. Because the anchorage clips are separate there will be no kinetic loading on one anchorage clip due to the movement of another anchorage clip. Each anchorage clip will simply move with the tissue wall. Ideally the anchorage clip is resilient to assist in the anchoring of the plug. The resilience of the anchorage clip will exert a light pressure on the surrounding wall of the occlusion and this is to be desired.
20

Preferably the clips are circumferentially spaced-apart with respect to the plug.

25 Alternatively or additionally the clips may be axially spaced-apart longitudinally with respect to the plug.

In a particularly preferred embodiment at least one and preferably each clip exerts a radial force to anchor the plug in an opening.

- 4 -

Ideally, at least one and preferably each clip exerts a longitudinal axial force in at least one and preferably two opposite directions to anchor to tissue or a vessel wall disposed therebetween.

- 5 In a preferred embodiment of the invention when the opening forms a through-hole and the body member projects beyond the opening and across the wall on both sides thereof, the clip is of substantially C shape having a pair of retaining arms projecting from a central support stock housed within the plug.
- 10 Ideally the retaining arms are inclined away from the stock towards each other and in this latter embodiment it is preferable that each retaining arm is cranked adjacent its free end towards the other.
- 15 The arm may be of forked construction having a plurality of splayed apart prongs and in this latter construction it may be a bifurcated arm.
- 20 In another embodiment of the invention the free end of the retaining arm terminates in an enlarged end portion forming a bearing member. Ideally the bearing member is formed by an elongate flat plate in turn forming with each arm at its free end a T piece, the plates forming tissue embracing plates.
- 25 In one embodiment of the invention the clip is in the form of a plurality of arms connected adjacent one end and diverging outwardly and upwardly therefrom for incorporating in the plug, the arms exerting an outward force on the tissue wall.
- In a modification of this latter embodiment of the invention the clip is in the form of a pair of arms in a V shape.

- 5 -

In one particular embodiment of this latter form of occluder the body member projects beyond the opening and across the wall and at least one of the arms has an extension piece extending into the body member where it projects across the wall.

5

Ideally in this latter embodiment the extension piece is cranked inwardly to exert an anchoring force on the wall.

When the opening forms a through-hole and the body member lies beyond the
10 opening and across the wall on both sides thereof the clips are so arranged that their extension pieces exert an anchorage force on both sides of the wall.

15

The anchorage clips may be substantially round in cross section but in some embodiments the retaining arms and stock may be substantially rectangular in cross-section.

20

Preferably the clip is manufactured from a medical implant material chosen to operate within its elastic deformation range, a particularly suitable material being Nitinol. Even more ideally, the anchorage clip is manufactured from a medical implant material which is radiopaque. Preferably, the anchorage clips will also have radiopaque markers at different sites of the arms and extension pieces to aid accurate positioning of the occluder.

25

In an alternative embodiment of the invention, the body member of the defect occluder is formed of, or at least coated with a biologically compatible material which contains radiopaque particles.

A particularly suitable number of clips is three or four.

- 6 -

Ideally the clips are totally encapsulated within the occluder, but may be only partially encapsulated.

Detailed Description of the Invention

5

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only described with reference to the accompanying drawings in which:

10

Fig. 1 is a side view of a defect occluder according to the invention;

Fig. 2 is a plan view of the occluder of Fig. 1;

Fig. 3 is a sectional view in the direction of the arrows III-III of Fig. 1;

15

Fig. 4 is a sectional view in the direction of the arrows IV-IV of Fig. 2;

Fig. 5 is a perspective view of a clip according to the invention forming part of the occluder of Figs. 1 to 4;

20

Fig. 6 is a side view of the clip of Fig. 5;

Fig. 7 is a sectional view similar to Fig. 4 showing the occluder mounted in a tissue wall having a defect opening;

25

Fig. 8 is a perspective view of another construction of clip;

Fig. 9 is a perspective view of a still further construction of clip;

30

Fig. 10 is a perspective view of another construction of clip;

- 7 -

Fig. 11 is a perspective of a still further construction of clip;

5 Fig. 12 is a sectional view of a still further defect occluder according to
the invention;

Fig. 13 is a side view of an alternative construction of occluder according
to the invention;

10 Fig. 14 is a plan view of the occluder of Fig. 13;

Fig. 15 is a sectional view in the direction of the arrows XV-XV of Fig.
14;

15 Fig. 16 is a sectional view in the direction of the arrows XVI-XVI of Fig.
14;

Fig. 17 is a side view of a still further occluder according to the invention;

Fig. 18 is a sectional view of the occluder of Fig. 17;

20 Fig. 19 is a sectional view similar to Fig. 18 of a still further construction
of occluder according to the invention;

25 Fig. 20 is a sectional view similar to Fig. 18 of another occluder according
to the invention;

Fig. 21 is a sectional view of a still further defect occluder in a tissue wall;

30 Fig. 22 is a sectional view of another defect occluder according to the
invention in a tissue wall;

- 8 -

Fig. 23 is a perspective view of an alternative construction of clip according to the invention; and

5 Fig. 24 is a perspective view of a still further construction of clip according to the invention.

Referring to the drawings and initially to Figs. 1 to 7 thereof, there is illustrated a defect occluder indicated generally by the reference numeral 1. The defect
10 occluder 1 has a body member formed from a compressible polymeric foam with an open cell structure which renders it highly compressible and flexible and comprises a pair of spaced apart inner and outer legs formed by discs 2 and 3 joined by a connecting post in the form of a narrowed plug 4. Encapsulated within the body member are three spaced apart separate reinforcing and/or anchorage clips 5. In this case each of the clips 5 is of substantially C shape having a pair of retaining arms 6 projecting from a central support stock 7. Each arm 6 is inclined inwardly away from the stock 7 towards each other. It will be noted that each retaining arm 6 is cranked at its free end 8.

20 Referring now to Fig. 7 the defect occluder 1 is shown mounted in a tissue wall 10 having an opening 11 and two exterior surfaces 12 one on either side of the wall 10. The body member lies beyond the opening 11 and across the wall on both sides thereof to contact both exterior surfaces 12. The defect occluder 1 will incorporate suitable gripping means or the like to allow deployment, none of
25 which is described in this specification as both the deployment and use are conventional. Because the anchorage clips 5 are separate and spaced apart they will not be under appreciable flexural or rotational load and thus there will be no dynamic load likely to cause metal fatigue.

- 9 -

Fig. 8 shows an alternative construction of clip indicated generally by the reference numeral 14 manufactured from a short small plate of Nitinol material.

5 Fig. 9 illustrates a still further construction of clip indicated generally by the reference numeral 15 having a substantially C shaped body 16 mounting at each free end an enlarged end portion forming a bearing member. The bearing member is formed by a flat plate 17 as a T piece. The plates 17, in use, are tissue embracing plates.

10 Referring now to Fig. 10 there is illustrated an alternative construction of clip indicated generally by the reference numeral 20. The clip 20 is of substantially C shape having a central support stock 21 carrying retaining arms 22, which are of forked construction having a plurality of splayed apart prongs 23 to enhance resiliency and anchoring.

15 15 Fig. 11 illustrates a still further construction of anchorage clip indicated generally by the reference numeral 25, again of substantially C shape having bifurcated retaining arms 26 projecting from a stock 27.

20 20 It will be appreciated that many forms of clip may be used and that any number of clips may be used. It will also be appreciated that in many instances one clip may be all that is required for efficient anchorage.

25 While in general the anchorage clips will be encapsulated fully in the defect occluder as shown in the above embodiments, it is envisaged that this may not always be necessary and those skilled in the art will readily appreciate this. Fig. 12 illustrates such a defect occluder indicated generally by the reference numeral 27 in which parts similar to those described with reference to Figs. 1 to 7 are identified by the same reference numerals. It will be seen that in this embodiment, the clip 5 is only partially encapsulated within the body member.

- 10 -

Referring now to Figs. 13 to 16 inclusive there is illustrated an alternative construction of occluder device indicated generally by the reference numeral 30, in which occluder device is substantially similar in construction to the occluder device of Figs. 1 to 7 inclusive and in which parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment, the only difference between it and the occluder device 1 is that there are provided clips indicated generally by the reference numeral 35 again manufactured from Nitinol wire, in which clips 35 are of substantially V shape, comprising a pair of arms 36, each having extension pieces 37 which incline downwardly and lie across the discs 2 and 3 and thus across the exterior surface of the wall. In this embodiment there are four clips, two of which have extension pieces which project into the disc 2 and the other two project into the disc 3 as can be seen from Figs. 15 and 16. In this case the clips are axially spaced-apart longitudinally with respect to the plug.

It will be appreciated that the arms 36 will splay apart so as to cause the plug 4 to sit tightly within a defect opening, while the extension pieces 37 will further cause the discs 2 and 3 to remain in place.

Referring to Figs. 17 and 18 there is illustrated another type of defect occluder indicated generally by the reference numeral 40 again of foamed plastics material having a plug 41 and a disc or flange 42 within which is encapsulated a number of separate clips identical to the clips 35 described above with reference to Figs. 13 to 16 (inclusive) and thus identified by the same reference numerals.

Referring to Fig. 19 there is illustrated an alternative construction of occluder indicated generally by the reference numeral 50, parts similar to those of the occluder 40 described with reference to Figs. 17 and 18 are identified by the same reference numerals. In this embodiment the occluder 50 is provided with

- 11 -

at least one and preferably a number of separate clips 55. Each clip 55 has only one extension piece 56, but in all other respects is substantially similar to the clip 35 of the embodiment of Figs. 17 and 18. Preferably there are a number of such separate clips.

5

In Fig. 20 there is illustrated a still further construction of defect occluder indicated generally by the reference numeral 60 in which parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment there is provided a simple form of clip indicated generally by the reference numeral 61 comprising a pair of arms 62 forming a clip of substantially V shaped configuration. The arms 62 will press outwards to cause the plug 41 to lie snugly within a defect opening. Preferably there are a number of such separate clips 61.

15

Referring to Fig. 21 there is illustrated a still further defect occluder indicated generally by the reference numeral 70 comprising a simple plug 71 of a compressible material having a clip 62 mounted therein, again parts similar to those described with reference to the previous drawings are identified by the same reference numerals. The advantage of the defect occluder 70 of this latter embodiment is that there will be no projecting surfaces above the face 12. Again, there may be a number of such clips 62.

20
25

Referring to Fig. 22 there is illustrated a still further defect occluder indicated generally by the reference numeral 80 in which in which parts similar to those described with reference to Fig. 21 are identified by the same reference numerals. In this embodiment the clips 2 are shorter than heretofore and can be placed one above the other as illustrated or circumferentially spaced around the plug with alternate upwardly and downwardly facing clips 62.

- 12 -

Referring to Fig. 23 there is illustrated an alternative construction of clip, indicated generally by the reference numeral 90 comprising a plurality of arms 91 connected together at one end 92 and diverging outwardly and upwardly from the end 92. The arms 91 will exert an outwardly directed force similar to that exerted by the clips of Figs. 15 onwards.

Referring now to Fig. 24 there is illustrated a still further construction of clip indicated generally by the reference numeral 95 which is somewhat similar to the clip illustrated in Fig. 23. In this embodiment the clip 95 comprises three arms 96 connected together at one free end 97 and diverging upwardly and outwardly therefrom, each arm 96 has an extension piece 97 which inclines downwardly and would, for example, lie across the tissue wall, such as, for example, when incorporated in the occluders of Figs. 13 to 16, or Figs. 17 and 18, or indeed many of the other occluders as illustrated.

It will be appreciated that as with the previously described occluder device of PCT Patent Application No. PCT/IE97/00037 (WO 97/41779) that the body member will have a 3-dimensional resiliently compressible polymeric construction but any other suitable compressible material may be used.

The anchorage clip according to the invention may be manufactured from any suitable medical implant grade metal. Preferably, the material is radiopaque and the clips can incorporate radiopaque markers at specific positions or sites to aid accurate positioning of the occluder on deployment. All that is required is that the metal operate in its area of elastic deformation and will not deform over time. As mentioned above, a particularly suitable material is Nitinol. The clips are preferably manufactured from wire substantially circular or rectangular in cross-section. The defect occluder is formed of or at least coated with a biologically compatible material. This material may also contain radiopaque particles.

- 13 -

While the only openings illustrated have been through-holes, it will be appreciated that this is not necessarily so.

- 5 In the specification the terms "comprise, comprises, comprised and comprising" or any variation thereof and the terms "include, includes, included and including" or any variation thereof are considered to be totally interchangeable and they should all be afforded the widest possible interpretation and vice versa.
- 10 The invention is not limited to the embodiments hereinbefore described, but may be varied in both construction and detail within the scope of the claims.

15

- 14 -

CLAIMS

1. A transcatheter occluder device for closing an opening in a tissue wall or a vessel wall, the device comprising: -

5

a body member formed from a material which is substantially self-supporting to hold a desired occluder shape, but is resiliently compressible for transcatheter deployment;

10

the material being a biologically compatible material or coated with a biologically compatible material;

the body member including a plug for closing the opening; and

15

the body member having retaining means for retaining the plug in the opening;

characterised in that the occluder includes a separate anchorage clip which is incorporated in the body member.

20

2. A device as claimed in claim 1 wherein the anchorage clip is resilient to assist in the anchoring of the plug.

3. A device as claimed in claim 1 or 2 wherein the occluder includes at least two separate anchorage clips.

25

4. A device as claimed in claim 3 wherein the clips are circumferentially spaced-apart with respect to the plug.

- 15 -

5. A device as claimed in claim 3 or 4 wherein the clips are axially spaced-apart longitudinally with respect to the plug.
6. A device as claimed in any preceding claim wherein at least one clip exerts a radial force to anchor the plug in an opening.
5
7. A device as claimed in any preceding claim wherein at least one clip exerts a longitudinal axial force to anchor the plug in an opening.
- 10 8. A device as claimed in claim 7 wherein the clip exerts a longitudinal axial force in at least one direction.
9. A device as claimed in claim 7 or 8 wherein the clip exerts a longitudinal axial force in two generally opposite directions to anchor to tissue or a vessel wall disposed therebetween.
15
10. A device as claimed in any preceding claim wherein the clip is generally c-shaped having a central stock and a pair of retaining arms extending from the central stock.
20
11. A device as claimed in claim 10 wherein the arms of the clip converge towards one another.
12. A device as claimed in claim 10 or 11 wherein at least one of the retaining arms is of forked construction.
25
13. A device as claimed in any of claims 10 to 12 wherein at least one of the retaining arms is bifurcated.

- 16 -

14. A device as claimed in any of claims 10 to 13 wherein at least one of the retaining arms is trifurcated.
15. A device as claimed in any preceding claim wherein the retaining clip includes at least one retaining arm having a free end.
5
16. A device as claimed in claim 15 wherein the retaining arm is turned inwardly adjacent to the free end.
- 10 17. A device as claimed in claim 15 or 16 wherein the arm terminates in an enlarged end portion.
18. A device as claimed in any of claims 15 to 17 wherein the arm includes an extension piece.
15
19. A device as claimed in any of claims 15 to 18 wherein the extension piece extends from the end of the arm.
20. A device as claimed in claim 18 or 19 wherein the extension piece comprises a generally flat extension member.
20
21. A device as claimed in any preceding claim wherein portion of the retaining clip extends beyond the margins of the body member.
25
22. A device as claimed in any of claims 1 to 9 wherein at least one retaining clip is generally V-shaped.
23. A device as claimed in any preceding claim wherein at least one clip is generally curvilinear in transverse cross section over at least portion of its length.
30

- 17 -

24. A device as claimed in any preceding claim wherein at least one clip is generally circular in transverse cross section over at least portion of its length.

5

25. A device as claimed in any preceding claim wherein at least one clip is generally rectilinear in transverse cross section over at least portion of its length.

10

26. A device as claimed in any of claims 2 to 19 wherein at least two of the clips are identical.

27. A device as claimed in claim 26 wherein the clips are generally oppositely directed.

15

28. A device as claimed in any of claims 2 to 27 in which the clip comprises at least two arms interconnected adjacent one end, the arms diverging outwardly towards a free end thereof.

20

29. A device as claimed in claim 28 wherein the body member projects beyond the opening and across the wall and at least one of the arms has an extension piece extending into the body member where it projects across the wall.

25

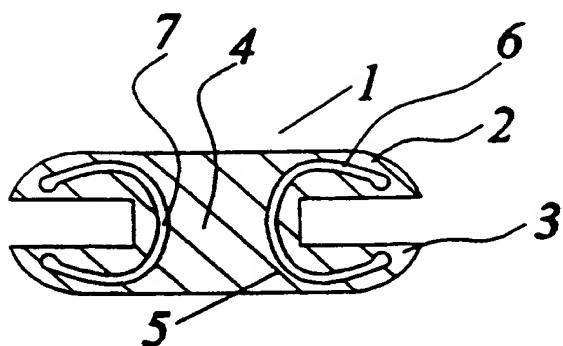
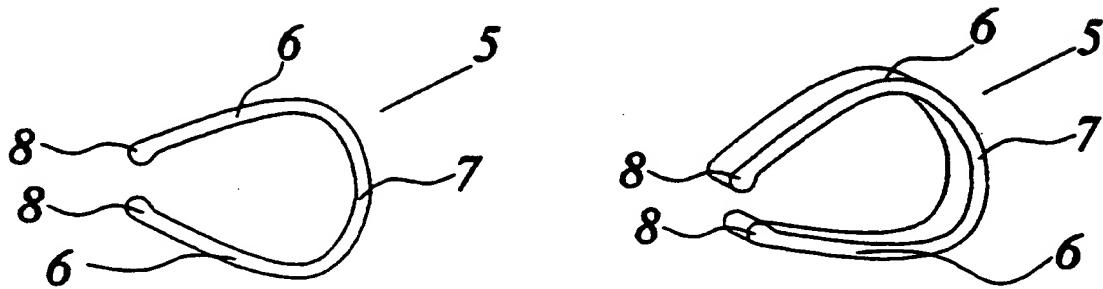
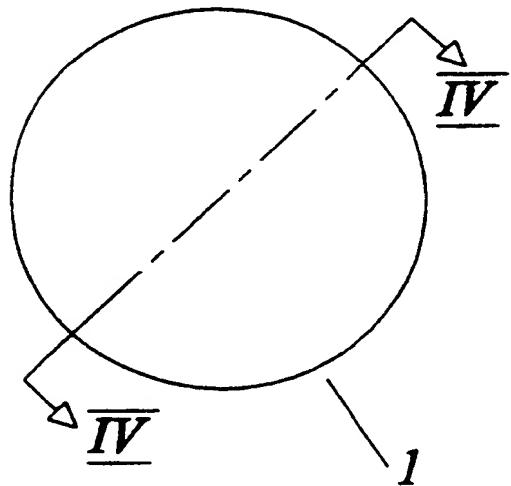
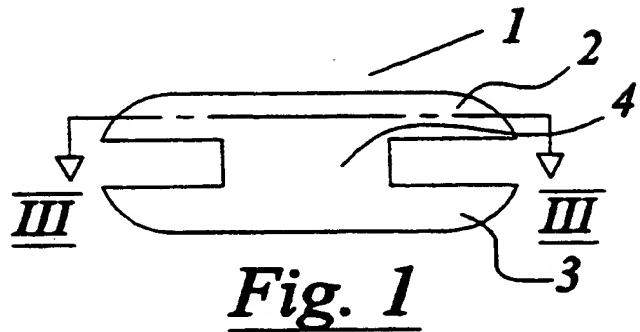
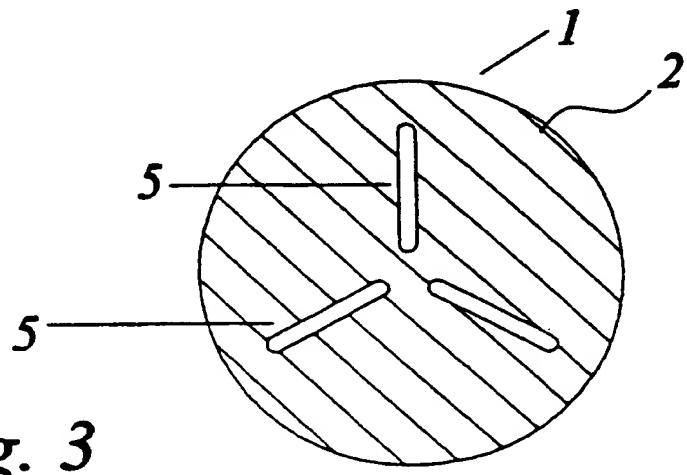
30. A device as claimed in any preceding claim wherein the clip is resilient to assist in anchoring of the plug in the opening.

31. A device as claimed in any preceding claim where the clip is of a shape memory material.

30

- 18 -

32. A device as claimed in any preceding claim wherein the clip is of Nitinol.
33. A device as claimed in any preceding claim wherein the clip is of a radiopaque material or includes a radiopaque marker.
5
34. A device as claimed in any preceding claim wherein the body member is formed substantially from an open cell polymeric i.e. foam material.
35. A device as claimed in any preceding claim wherein the clip is totally encapsulated within the body member.
10
36. A device as claimed in any preceding claim wherein the body member in a deployed configuration is of generally T-shape in transverse cross section.
15
37. A device as claimed in any of claims 1 to 35 wherein the body member comprises an inner leg and an outer leg with a connecting post extending therebetween.
38. A device as claimed in claim 37 wherein the inner and outer legs are generally disc-shaped.
20
39. A device as claimed in any preceding claim wherein the body member includes radiopaque marking means.
40. An occluder device substantially as hereinbefore described with reference to the accompanying drawings.
25

1/6*Fig. 4**Fig. 6**Fig. 5**Fig. 2**Fig. 1**Fig. 3*

2/6

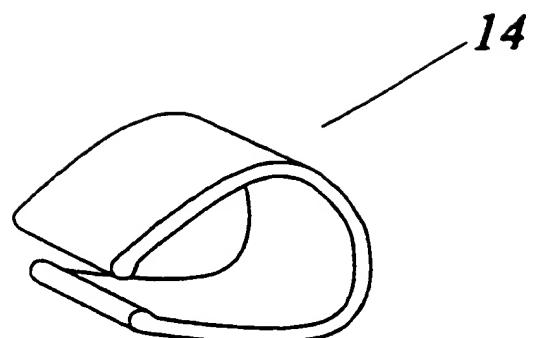


Fig. 8

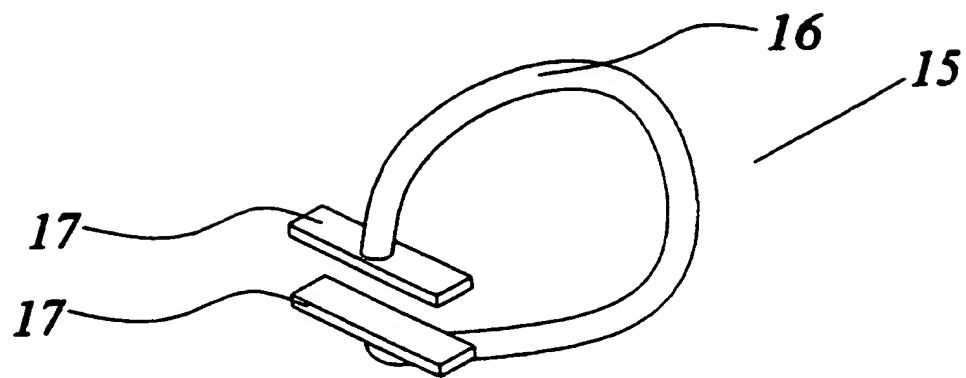


Fig. 9

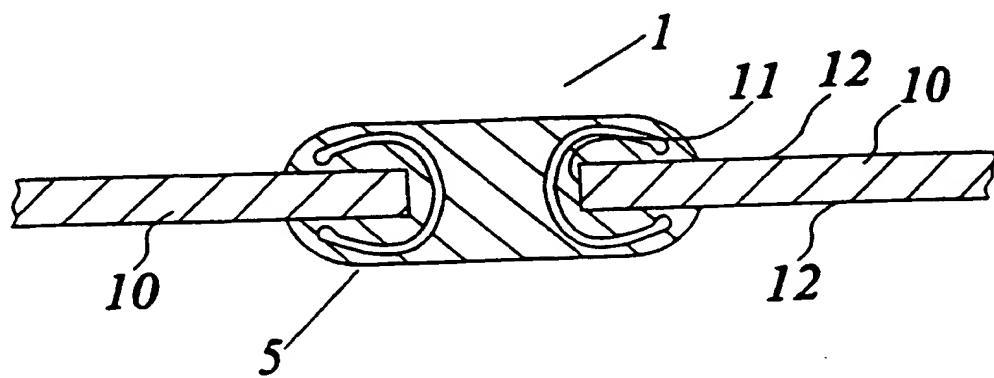


Fig. 7

3/6

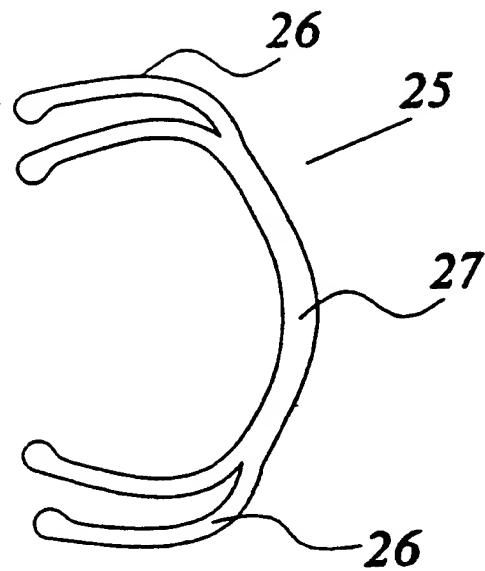


Fig. 11

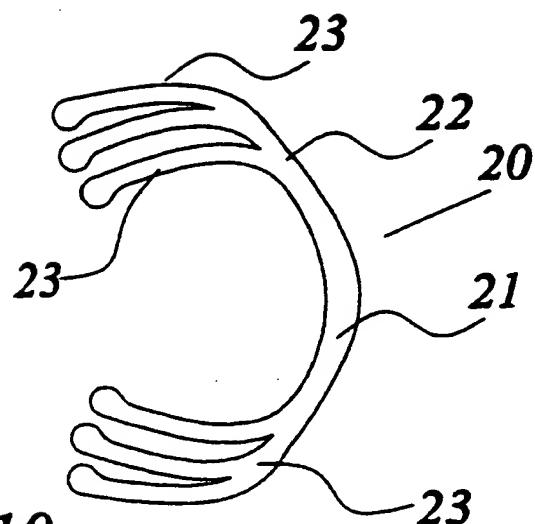


Fig. 10

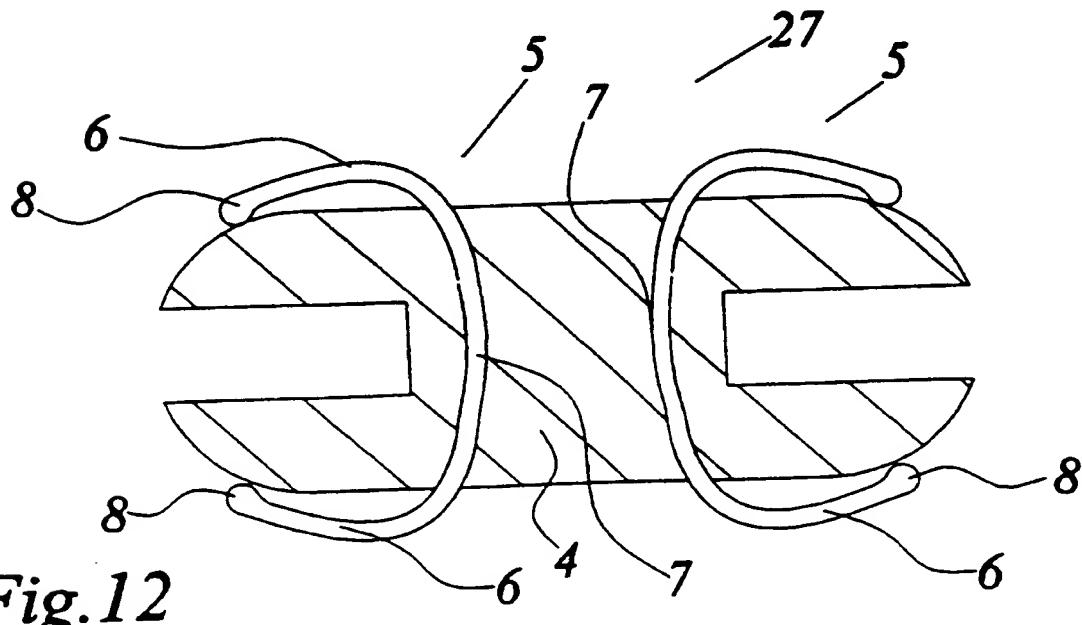
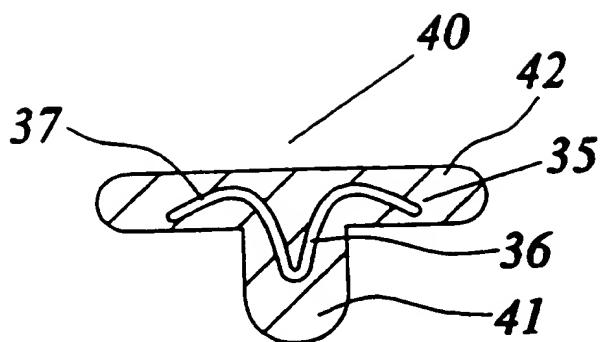
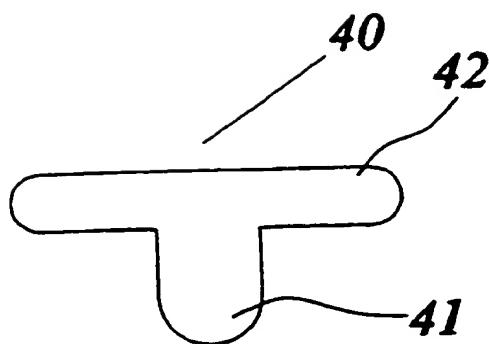
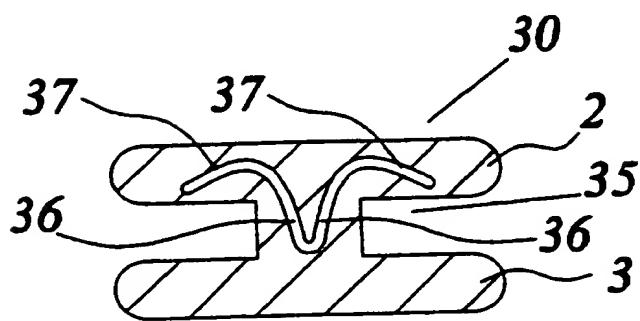
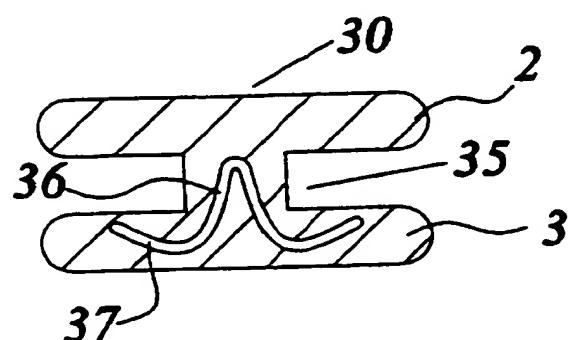
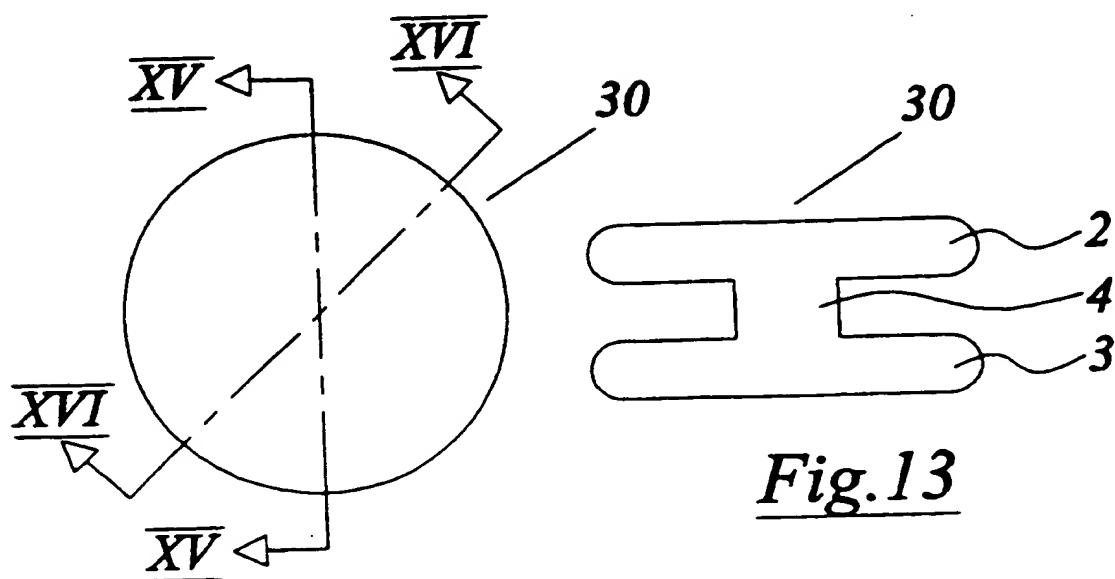
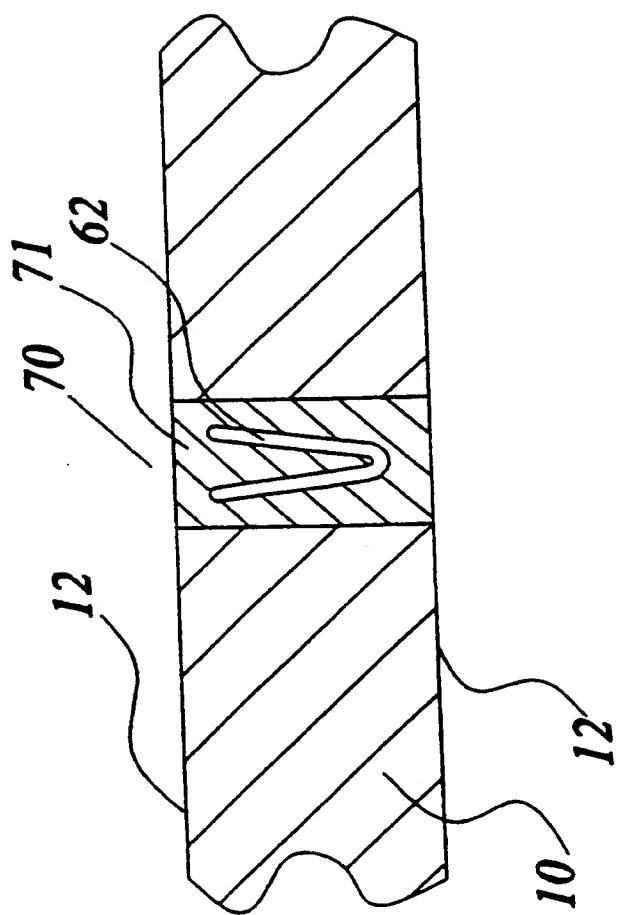
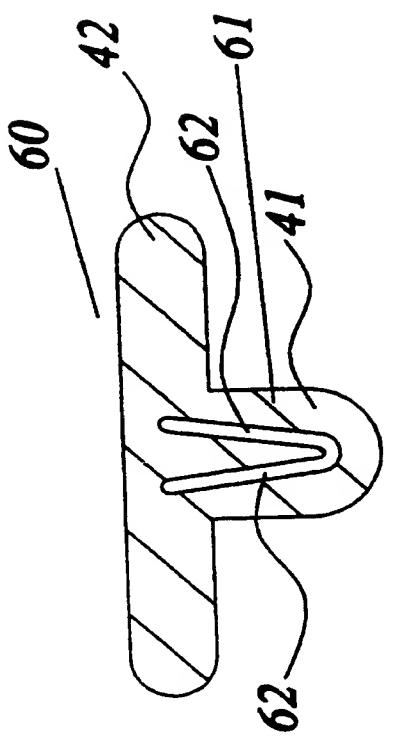
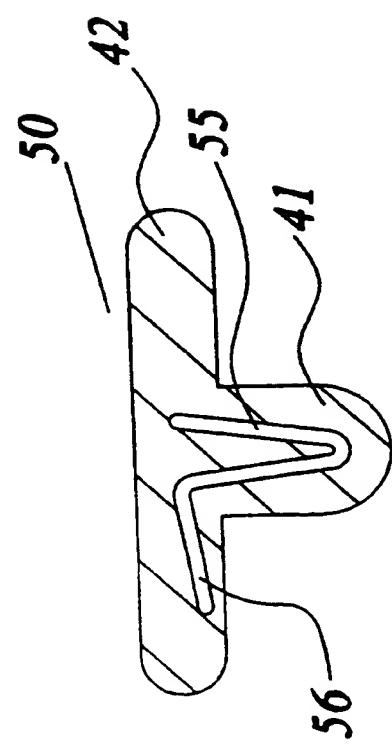


Fig. 12

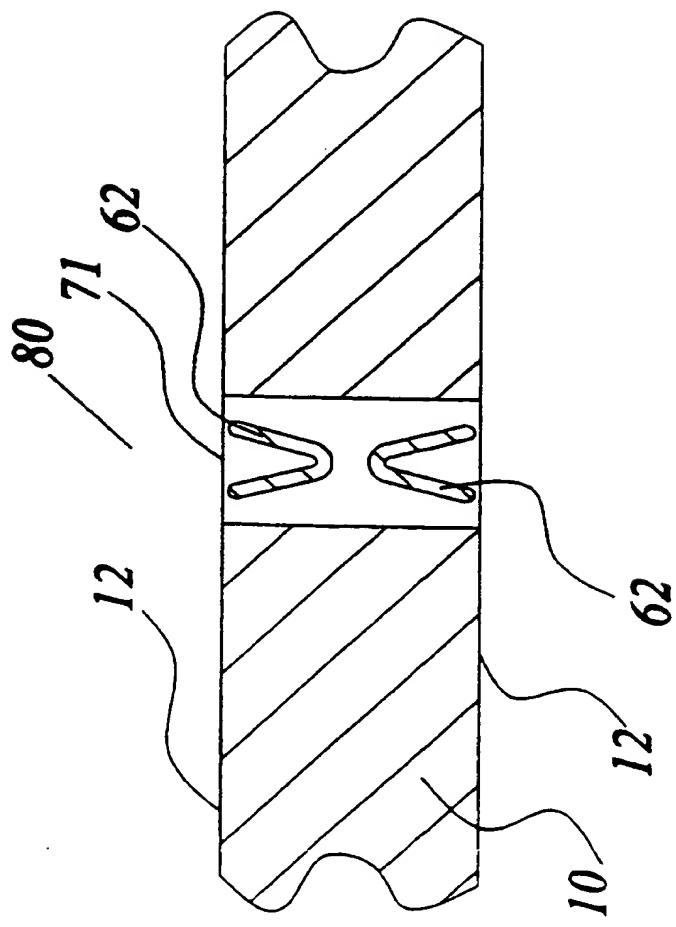
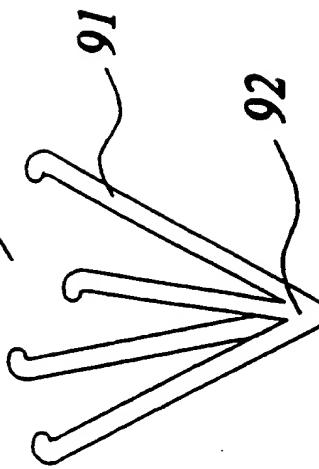
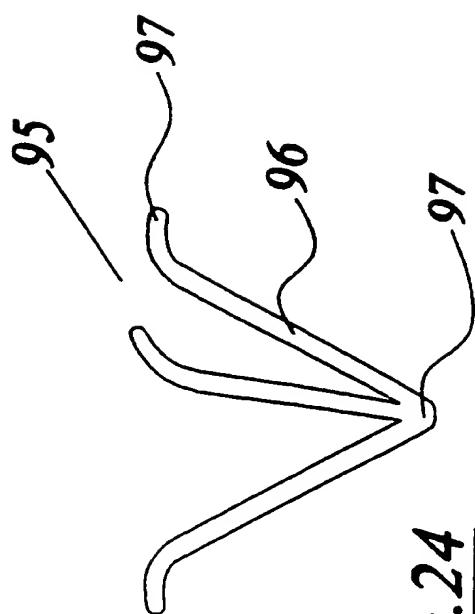
4/6

Fig. 18Fig. 17Fig. 15Fig. 16Fig. 14Fig. 13

5/6

Fig.21Fig.20Fig.19

6/6

Fig. 22Fig. 23Fig. 24

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 00/00096

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 41778 A (SALVIAC) 13 November 1997 (1997-11-13) cited in the application	1, 2, 15, 16, 23-25, 28-30, 33-40
Y	figures 17, 18 ---	17-20
X	WO 98 27868 A (GORE) 2 July 1998 (1998-07-02) page 10 -page 12; figures 1-7 ---	1-5, 7-9, 15, 16, 25-33, 35, 37-40
X	DE 297 14 242 U (APPLIED BIOMETRICX) 10 December 1998 (1998-12-10) page 15, paragraph 2; figures 1-3 page 10, paragraph 5 ---	1, 6, 15, 17-19, 21, 28
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

4 December 2000

27.12.2000

Name and mailing address of the ISA

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Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

Int'l. Appl. No.
PCT/IE 00/00096

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 01433 A (YOON) 6 February 1992 (1992-02-06)	1
A	page 19, last paragraph; figures 13,23-25 ---	6,22
X	DE 94 13 645 U (SCHNEIDT) 27 October 1994 (1994-10-27) figures 3,4 ---	1,21
Y	WO 98 18389 A (CONLAN) 7 May 1998 (1998-05-07)	17-20
A	figures 6-9 ---	10
A	EP 0 545 091 A (BARD) 9 June 1993 (1993-06-09) ---	
A	US 5 649 950 A (WHITTAKER) 22 July 1997 (1997-07-22) -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 00/00096

Box 1 Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

 2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

 3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II. Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

As a result of the prior review under R. 40.2(e) PCT,
no additional fees are to be refunded.

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
 2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
 3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
 4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/IE 00 00096

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-5,7-9,15,16,23-40

Occluder with multiple incorporated clips

2. Claims: 1,6,22

Occluder incorporating clip(s) exerting radial force on opening

3. Claims: 1,10-14

Occluder incorporating C-shaped clip(s) extending either side of the opening

4. Claims: 1,15-20

Occluder incorporating clip(s) with enlarged end or extension to the clip arms

5. Claims: 1,21

Occluder with clip(s) only partially embedded in the body

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 00/00096

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9741778	A	13-11-1997	US 5904703 A AU 3186897 A EP 0900051 A	18-05-1999 26-11-1997 10-03-1999
WO 9827868	A	02-07-1998	US 5879366 A AU 5804598 A BR 9713765 A EP 0961579 A US 6080182 A	09-03-1999 17-07-1998 01-02-2000 08-12-1999 27-06-2000
DE 29714242	U	10-12-1998	AU 8678998 A BR 9811124 A EP 1018943 A WO 9907289 A	01-03-1999 22-08-2000 19-07-2000 18-02-1999
WO 9201433	A	06-02-1992	US 5074840 A US 5374261 A AT 173912 T AU 689397 B AU 1002597 A AU 699523 B AU 5286298 A AU 672722 B AU 7762894 A AU 667787 B AU 7762994 A AU 676383 B AU 7763094 A AU 651843 B AU 8445191 A CA 2088070 A DE 69130567 D DE 69130567 T EP 0540682 A ES 2125238 T JP 5509024 T KR 9604969 B US 5451204 A US 5827215 A US 5484426 A US 5392787 A US 5514085 A US 5439457 A US 5556376 A US 5407423 A US 5599292 A US 5649902 A US 5755724 A US 5733252 A US 5700239 A US 5843017 A US 5836953 A	24-12-1991 20-12-1994 15-12-1998 26-03-1998 27-02-1997 03-12-1998 21-05-1998 10-10-1996 12-01-1995 04-04-1996 12-01-1995 06-03-1997 12-01-1995 04-08-1994 18-02-1992 25-01-1992 14-01-1999 12-05-1999 12-05-1993 01-03-1999 16-12-1993 18-04-1996 19-09-1995 27-10-1998 16-01-1996 28-02-1995 07-05-1996 08-08-1995 17-09-1996 18-04-1995 04-02-1997 22-07-1997 26-05-1998 31-03-1998 23-12-1997 01-12-1998 17-11-1998
DE 9413645	U	27-10-1994	DE 29500381 U EP 0698373 A	20-07-1995 28-02-1996
WO 9818389	A	07-05-1998	AU 4490097 A	22-05-1998

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IE 00/00096

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
EP 545091 A	09-06-1993	CA	2082224 A		06-05-1993
		DE	69229539 D		12-08-1999
		DE	69229539 T		17-02-2000
		JP	6189971 A		12-07-1994
		US	5451235 A		19-09-1995
US 5649950 A	22-07-1997	US	5626599 A		06-05-1997
		US	5486193 A		23-01-1996
		CA	2087906 A		23-07-1993
		DE	69312756 D		11-09-1997
		DE	69312756 T		02-01-1998
		EP	0556564 A		25-08-1993
		ES	2104963 T		16-10-1997
		JP	6022970 A		01-02-1994

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